

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application No.: 10/081,166

Filing Date: 2-22-02

Applicant: Shon D. Steger et al.

Group Art Unit: Unknown

Examiner: Unknown

Title: METHOD AND APPARATUS FOR BONE FRACTURE  
FIXATION

Attorney Docket: 5490-000127/CPC



Hon. Commissioner of Patents and Trademarks  
Washington, D.C. 20231

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicant hereby submits an Information Disclosure Statement for consideration by the Examiner.

**I. LIST OF PATENTS, PUBLICATIONS, AND OTHER INFORMATION**

The patents, publications and other information submitted for consideration by the Office (except unpublished U.S. patent applications) are listed on Form 1449 attached hereto.

**II. COPIES**

A. X Submitted herewith is a legible copy of (i) each U.S. patent application publication and U.S. and foreign patent; (ii) each publication or that portion which caused it to be listed; (iii) for each cited pending U.S. application, the application specification including the claims, and any drawing of the application which caused it to be listed including the claims directed to that portion; and (iv) all other information or that portion which caused it to be listed.

B.     Any patents, publications or other information which are listed on Form 1449 or on the copies of PTO-892, but which are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Serial Number

U.S. Filing Date

C. \_\_\_ This is a PCT application in the entry of the National Phase in the United States. A copy of the International Search Report is attached for the Examiner's information. The documents listed on the International Search Report are listed on the attached Form-1449 for consideration by the Examiner and for listing on any patent resulting from this application. Since the International Search Report was from the US, EPO, or JPO search authorities, copies of these references should have been supplied to the USPTO under the trilateral agreement and are believed to be in the file of the above-identified application. (MPEP 1893.03(g))

III. CONCISE EXPLANATION OF THE RELEVANCE (check at least one box)

A. X Except as may be indicated below in (B), all of the patents, publications or other information are in the English language (concise explanation not required).

B. \_\_\_ A concise explanation of the relevance of each patent, publication or other information listed that is not in the English language is as follows (see 37 C.F.R. § 1.98(a)(3)):

1. \_\_\_ See the attached foreign patent office communication from a counterpart foreign application:
2. \_\_\_ English translations are provided for:
3. \_\_\_ Other:

C. \_\_\_ The following additional information is provided for the Examiner's consideration.

IV. CROSS REFERENCE TO RELATED APPLICATION(S)

A. \_\_\_ The Examiner is advised that the following co-pending application(s) contain(s) subject matter that may be related to the present application. By bringing this(these) application(s) to the Examiner's attention, Applicant(s) does(do) not waive the confidentiality provisions of 35 U.S.C. § 122.

Serial No.

Filing Date

Art Unit

V. THIS IDS IS BEING FILED UNDER

A. X 37 C.F.R. § 1.97(b): (check only one box)

1. X within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d) (37 C.F.R. § 1.97(b)(1)). No fee or certification is required.

2. \_\_\_\_ within three months of the date of entry of the national stage as set forth in §1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or certification is required.

3. \_\_\_\_ before the mailing of a first Office Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or certification is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e) below; or, if no certification has been made, charge our deposit account a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

4. \_\_\_\_ before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No fee or certification is required.

B. \_\_\_\_ 37 C.F.R. § 1.97(c): (check only one box)

- before the mailing date of either any Final Office Action under 37 C.F.R. § 1.113, a Notice of Allowance under 37 C.F.R. § 1.311, or an action that otherwise closes prosecution.

1. \_\_\_\_ No certification; therefore, a fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).

2. \_\_\_\_ See the certification below. No fee is required.

C. \_\_\_\_ 37 C.F.R. § 1.97(d):

- after the mailing date of either a Final Office Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311, yet on or before payment of the issue fee.

1. \_\_\_\_ See the certification below. A fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).

VI. CERTIFICATION UNDER 37 C.F.R. § 1.97(e): (check only one box)

The undersigned hereby certifies that:

A. \_\_\_\_ each item of information contained in this IDS was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(1)). See further statement under 37 C.F.R. § 1.704(d) below in section VII, if applicable; or

B. \_\_\_ no item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(2)).

C. \_\_\_ Some of the items of information were first cited in a communication from a foreign patent office. As to this information, the undersigned hereby certifies that each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby certifies that no item of this remaining information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS.

VII. STATEMENT UNDER 37 CFR 1.704(d)

The undersigned hereby states that:

\_\_\_ each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in 37 C.F.R. 1.56(c) more than thirty days prior to the filing of this IDS.

VIII. PAYMENT OF FEES (check only one box)

A. \_\_\_ A check in the amount of \$180.00 is enclosed for the above-identified fee.

B. \_\_\_ Please charge Deposit Account No. 08-0750 in the amount of \$180.00 for the above-indicated fee. A duplicate copy of this paper is attached.

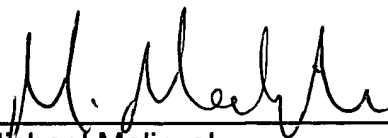
The above references are being cited only in the interest of candor and without any admission that they constitute statutory prior art, contain matter which anticipates the invention, or which would render the same obvious, either singly or in combination, to a person of ordinary skill in the art. Furthermore, this Information Disclosure Statement shall not be construed as a representation that a search has been made.

If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 08-0750.

Please charge any additional fees or credit any overpayment pursuant to 37 C.F.R. § 1.16 or § 1.17 to Deposit Account No. 08-0750.

Respectfully submitted,

Dated: May 17, 2002

By:   
Michael Malinzak  
Reg. No. 43,770

HARNESS, DICKEY & PIERCE, P.L.C.  
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FORM HDP-1449 (Based on Form PTO-1449)

**PATENT AND TRADEMARK OFFICE  
INFORMATION DISCLOSURE CITATION**

(Use several sheets if necessary)

Sheet 1 of 4

ATTORNEY DOCKET NO.

SERIAL NO.

5490-000127/CPC

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APPLICANT

Shon D. Steger et al.

FILING DATE

GROUP

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**U.S. PATENT DOCUMENTS**

Ref. Desig.	Examiner's Initials	Document Number	Date	Name	Class/ Subclass	(If appropriate) Filing Date
1.						

**FOREIGN PATENT DOCUMENTS**

Ref. Desig.	Examiner's Initials	Document Number	Date	Country	Class/ Subclass	Translation Yes	No
1.							

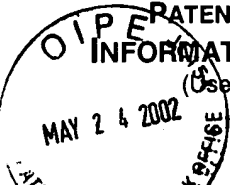
**OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)**

Ref. Desig.	Examiner's Initials	
1.		A Biomechanical Study of Median Sternotomy Closure Techniques, European Journal of Cardio-thoracic Surgery 15, A.R. Casha, L. Yang, P.H. Kay, M. Saleh, and G.J. Cooper (1999), Pgs. 365-369
2.		Biomechanical Study of Sternal Closure Techniques, Wen Cheng, MD, Duke E. Cameron, MD, Karen E. Warden, PhD, James D. Fonger, MD, and Vincent L. Gott, MD, Div. of Cardiac Surgery, The Johns Hopkins Medical Institutions, Baltimore, MD (1993), Pgs. 737-740
3.		Biomechanical Study of Sternal Closure Using Rigid Fixation Techniques in Human Cadavers, Wayne Ozaki, MD, Steven R. Buchman, MD, Mark D. Iannettoni, MD, and Elizabeth P. Frankenburg, BS, Sections of Plastic and Reconstructive Surgery, and Cardiothoracic Surgery, University of Michigan Medical Center, Ann Arbor, MI (1998), Pgs. 1660-1665
4.		Bite Forces Before and After Surgical Correction of Mandibular Prognathism, Edward Ellis III, DDS, Gaylord S. Throckmorton, PhD, and Douglas P. Sinn, DDS, American Assoc. of Oral and Maxillofacial Surgeons (1996), Pgs. 176-181

Examiner:

Date Considered:

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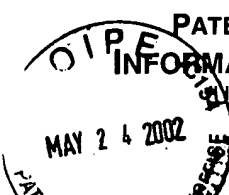
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OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)		
Ref. Desig.	Examiner's Initials	
5.		Catastrophic Hemorrhage on Sternal Reentry: Still a Dreaded Complication?, Fabrizio M. Follis, MD, Stuart B. Pett, Jr, JD, Kevin B. Miller, MD, Rose S. Wong, MD, R. Thomas Temes, MD, and Jorge A. Wernly, MD, Ann Thorac Surg 1999;68:2215-2219, 1999 The Society of Thoracic Surgeons (reprint)
6.		Chest Wall Stabilization Using Plate Fixation, John E. Sherman, MD, Andrew Salzberg, MD, Noel M. Raskin, MD, and Edward J. Beattie, MD, Annals of Thoracic Surgery (Oct. 1988), Pgs. 467-469
7.		Comparison of Habitual Masticatory Cycles and Muscle Activity Before and After Orthognathic Surgery, Riad E. Youssef, DDS, Gaylord S. Throckmorton, PhD, Edward Ellis III, DDS, MS, and Douglas P. Sinn, DDS, American Assoc. of Oral and Maxillofacial Surgeons (1997), Pgs. 699-708
8.		The Healing Sternum: A Comparison of Osseous Healing With Wire Versus Rigid Fixation, Larry A. Sargent, MD, Alan E. Seyfer, MD, Jeffery Hollinger, DDS, PhD, Roger M. Hinson, and Geoffrey M. Graeber, MD, Plastic Surgery Service, Walter Reed Army Medical Center and Institute of Research, and US Army Institute of Dental Research, Washington, D.C. (April 5, 1991), Pgs. 490-494
9.		Improved Sternal Fixation in the Correction of Pediatric Pectus Excavatum, Michael L. Bentz, MD, Marc I. Rowe, MD, and Eugene S. Wiener, MD, Case Report (1994) by Little, Brown and Company, Pgs. 638-641
10.		Improvement of Maximum Occlusal Forces After Orthognathic Surgery, Gaylord S. Throckmorton, PhD, Peter H. Buschang, PhD, and Edward Ellis III, DDS, 1996 American Assoc. of Oral and Maxillofacial Surgeons, 54:1080-1086
11.		Internal Fixation of the Sternum in Median Sternotomy Dehiscence, Christopher W. Chase, MD, John D. Franklin, MD, Daryl P. Guest, MD, and Donald E. Barker, MD, Dept. of Surgery at Univ. of Tenn. College of Medicine (Nov. 25, 1998), Pgs. 1667-1673
12.		Mechanical analysis of Midline Sternotomy Wound Closure, Walter E. McGregor, MD, Dennis R. Trumble, MS, and James A. Magovern, MD, The Journal of Thoracic and Cardiovascular Surgery, Vol. 117, Number 6, Pgs. 1144-1150
13.		Median Sternotomy Dehiscence, William S. Stoney, MD, et al., The Annals of Thoracic Surgery, Vol. 26, No. 5, November 1978, Pgs. 421-426

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14.		Median Sternotomy Wound Dehiscence: A Retrospective Case Control Study of Risk Factors and Outcome, A. J. Bryan, et al., Dept. of Cardiac Surgery, University Hospital of Wales, Cardiff, UK (1992), Pgs. 305-308
15.		Non-Union of Fractures of the Sternum, I. I. Mayba, MD, Winnipeg, Manitora, Canada, The Journal of Bone and Joint Surgery, Incorporated (1985), Pgs. 1091-1093
16.		Open Fixation of Sternal Fracture, Jerry Kitchens, MD, and J. David Richardson, MD, FACS, Louisville, Kentucky; Surgery, Gynecology & Obstetrics, October 1993, Vo. 177, Pgs. 176-177
17.		Paramedian Sternal Bone Plate Reinforcement and Wiring for Difficult Sternotomy Wounds, E. Clyde Smoot, MD, and Darryl Weiman, MD (1998) by Lippincott Williams & Wilkins, Pgs. 464-467
18.		A Polyurethane Foam Model for Characterizing Suture Pull-Through Properties in Bone; Joseph E. Hale, Donald D. Anderson, and Greg A. Johnson, Biomechanics Laboratory, Minneapolis Sports Medicine Center, Minneapolis, MN, www.asb-biomech.org/abstracts99/133 (4 pgs) (reprint)
19.		Repair of Sternal Dehiscence Using a Harrington Compression System, Mark D. Miller, P.A.-C, Robert G. Johnson, MD, and Jerome Naifeh, MD, Ann Thorac Surg 45:684-685, June 1988
20.		Rigid Internal Fixation of the Sternum in Postoperative Mediastinitis, Lawrence J. Gottlieb, MD, et al., Arch Surg/Vol. 129, May 1994, Pgs. 489-493
21.		Sternal Plating for the Treatment of Sternal Nonunion, Steven C. Hendrickson, MD, et al., Divisions of Cardiothoracic Surgery, Plastic and Maxillofacial Surgery, and Orthopaedic Surgery, Dept. of Surgery, Duke Univ. Medical Center and Durham Veterans Administration Hospital, Durham, NC (1996), Pgs. 512-518
22.		Sternal Salvage With Quantitative Bacteriology and Rigid Plate Fixation in Postoperative Mediastinitis: A 10 Year Experience, David H. Song, MD, et al., American Assoc. of Plastic Surgeons - 79th Annual Meeting (May 7-10, 2000), 3 Pages
23.		Prophylactic Rigid Plate Fixation for High Risk Sternotomies, David H. Song, MD, The University of Chicago Plastic and Reconstructive Surgery (2-23-01) 16 Pages

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24.		Superior Sternal Cleft: Construction With A Titanium Plate, Anita Hazaari, F.R.C.S., et al., Frenchay Hospital and Bristol Children's Hospital, Bristol, UK (Feb. 3, 1997), Pgs. 167-170
25.		Update on Sternal Osteosynthesis, Josef G. Vincent, MD, How To Do It, Institute of Thoracic, Cardiac and Vascular Surgery, Saint Radboud Univ. Hospital, Nijmegen, The Netherlands (March 14, 1985), Pgs. 216-218

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